

MAR 26 2000

K000013



510(k) SUMMARY

Applicant's Name and Address:

Acist Medical Systems, Inc.
7450 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344

Name of Contact Person:

Carl M. Beaurline
Vice President, Quality Assurance / Regulatory Affairs

Telephone and Fax Numbers:

Telephone – (612) 995-9319
Fax – (612) 941-4648

Address of Manufacturing and Sterilization Site:

Manufacturing: Acist Medical Systems, Inc.
7450 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344

Sterilization: Not applicable to this product.

Proprietary Name: Acist® Angiographic Injection System, Model R-2000

Common Name: Contrast Injector

Classification Name: Injector, Contrast Medium, Automatic

Classification Number: 870.1650

Class: II

Classification Panel: Cardiovascular

Product Code: IZQ

Description:

The Acist® Angiographic Injection System delivers contrast media to a catheter at a user-determined variable flow rate that can be instantaneously and continuously varied.

The system is comprised of the following elements:

- Injector Head with X-Ray Interface Port
- Control Panel
- Power Supply
- AC Power and Interconnect Cables

Not affected by this change, but provided with the system are the sterile disposable components. These are contained in two separate kits (D-1000 and H-1000) and include the Hand Controller, Contrast Syringe, and the valving and tubing to provide the interface between the system and the angiographic patient catheter

Predicate Device: Acist® Angiographic Injection System, Model CL100H, without the Radiology modification.

Indications for Use:

The Acist Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.



MAR 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carl M. Beaurline
Vice President, Quality Assurance/Regulatory Affairs
Acist Medical Systems, Inc
7450 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Re: K000013
Acist Angiographic Injection System
Regulatory Class: II (two)
Product Code: DXT
Dated: February 25, 2000
Received: February 29, 2000

Dear Mr. Beaurline:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chris Dillard III", written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000013

SECTION 6 – STATEMENT OF INDICATIONS FOR USE / LABELING

PART A - INDICATIONS FOR USE FORM

Page ____ of ____

510(k) Number:

Device Name: **Acist Angiographic Injection System**

Indications for Use:

The Acist Angiographic Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher M. Dillard

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number _____ OR

Over-The-Counter Use _____
(Optional Format 1-2-96)